

§ 405.201

- 405.2162 Condition: Staff of a renal dialysis facility or renal dialysis center.
- 405.2163 Condition: Minimal service requirements for a renal dialysis facility or renal dialysis center.
- 405.2164 Conditions for coverage of special purpose renal dialysis facilities.
- 405.2170 Condition: Director of a renal transplantation center.
- 405.2171 Condition: Minimal service requirements for a renal transplantation center.
- 405.2180 Termination of Medicare coverage.
- 405.2181 Alternative sanctions.
- 405.2182 Notice of sanction and appeal rights: Termination of coverage.
- 405.2184 Notice of appeal rights: Alternative sanctions.

Subparts V–W [Reserved]

Subpart X—Rural Health Clinic and Federally Qualified Health Center Services

- 405.2400 Basis.
- 405.2401 Scope and definitions.
- 405.2402 Basic requirements.
- 405.2403 Content and terms of the agreement with the Secretary.
- 405.2404 Terminations of agreements.
- 405.2410 Application of Part B deductible and coinsurance.
- 405.2411 Scope of benefits.
- 405.2412 Physicians' services.
- 405.2413 Services and supplies incident to a physician's services.
- 405.2414 Nurse practitioner and physician assistant services.
- 405.2415 Services and supplies incident to nurse practitioner and physician assistant services.
- 405.2416 Visiting nurse services.
- 405.2417 Visiting nurse services: Determination of shortage of agencies.

FEDERALLY QUALIFIED HEALTH CENTER SERVICES

- 405.2430 Basic requirements.
- 405.2434 Content and terms of the agreement.
- 405.2436 Termination of agreement.
- 405.2440 Conditions for reinstatement after termination by CMS.
- 405.2442 Notice to the public.
- 405.2444 Change of ownership.
- 405.2446 Scope of services.
- 405.2448 Preventive primary services.
- 405.2450 Clinical psychologist and clinical social worker services.
- 405.2452 Services and supplies incident to clinical psychologist and clinical social worker services.

PAYMENT FOR RURAL HEALTH CLINIC AND FEDERALLY QUALIFIED HEALTH CENTER SERVICES

- 405.2460 Applicability of general payment exclusions.

42 CFR Ch. IV (10–1–03 Edition)

- 405.2462 Payment for rural health clinic and Federally qualified health center services.
- 405.2463 What constitutes a visit.
- 405.2464 All-inclusive rate.
- 405.2466 Annual reconciliation.
- 405.2468 Allowable costs.
- 405.2470 Reports and maintenance of records.
- 405.2472 Beneficiary appeals.

AUTHORITY: Secs. 1102, 1861, 1862(a), 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 1302, 1395x, 1395y(a), 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

Subpart A [Reserved]

Subpart B—Medical Services Coverage Decisions That Relate to Health Care Technology

AUTHORITY: Secs. 1102, 1862 and 1871 of the Social Security Act as amended (42 U.S.C.1302, 1395y, and 1395hh).

SOURCE: 60 FR 48423, Sept. 19, 1995, unless otherwise noted.

§ 405.201 Scope of subpart and definitions.

(a) *Scope.* This subpart establishes that—

(1) CMS uses the FDA categorization of a device as a factor in making Medicare coverage decisions; and

(2) CMS may consider for Medicare coverage certain devices with an FDA-approved investigational device exemption (IDE) that have been categorized as non-experimental/investigational (Category B).

(b) *Definitions.* As used in this subpart—

Class I refers to devices for which the general controls of the Food, Drug, and Cosmetic Act, such as adherence to good manufacturing practice regulations, are sufficient to provide a reasonable assurance of safety and effectiveness.

Class II refers to devices that, in addition to general controls, require special controls, such as performance standards or postmarket surveillance, to provide a reasonable assurance of safety and effectiveness.

Class III refers to devices that cannot be classified into Class I or Class II because insufficient information exists to

determine that either special or general controls would provide reasonable assurance of safety and effectiveness. Class III devices require premarket approval.

Contractors refers to carriers, fiscal intermediaries, and other entities that contract with CMS to review and adjudicate claims for Medicare services.

Experimental/investigational (Category A) device refers to an innovative device believed to be in Class III for which “absolute risk” of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved and the FDA is unsure whether the device type can be safe and effective).

IDE stands for investigational device exemption. An FDA-approved IDE application permits a device, which would otherwise be subject to marketing clearance, to be shipped lawfully for the purpose of conducting a clinical trial in accordance with 21 U.S.C. 360j(g) and 21 CFR parts 812 and 813.

Non-experimental/investigational (Category B) device refers to a device believed to be in Class I or Class II, or a device believed to be in Class III for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type.

PMA stands for “premarket approval” and refers to a marketing application for a Class III device, which includes all information submitted with or incorporated by reference in the application in accordance with 21 U.S.C. 360e and 360j and 21 CFR 814.3(e).

Sponsor refers to a person or entity that initiates, but does not conduct, an investigation under an IDE.

§ 405.203 FDA categorization of investigational devices.

(a) The FDA assigns a device with an FDA-approved IDE to one of two categories:

(1) Experimental/Investigational (Category A) Devices.

(2) Non-Experimental/Investigational (Category B) Devices.

(b) The FDA notifies CMS, when it notifies the sponsor, that the device is categorized by FDA as experimental/investigational (Category A) or non-experimental/investigational (Category B).

(c) CMS uses the categorization of the device as a factor in making Medicare coverage decisions.

§ 405.205 Coverage of a non-experimental/investigational (Category B) device.

(a) For any device that meets the requirements of the exception at § 411.15(o) of this chapter, the following procedures apply:

(1) The FDA notifies CMS, when it notifies the sponsor, that the device is categorized by FDA as non-experimental/investigational (Category B).

(2) CMS uses the categorization of the device as a factor in making Medicare coverage decisions.

(b) If the FDA becomes aware that a categorized device no longer meets the requirements of the exception at § 411.15(o) of this chapter, the FDA notifies the sponsor and CMS and the procedures described in paragraph (a)(2) of this section apply.

§ 405.207 Services related to a non-covered device.

(a) *When payment is not made.* Medicare payment is not made for medical and hospital services that are related to the use of a device that is not covered because CMS determines the device is not “reasonable” and “necessary” under section 1862(a)(1)(A) of the Act or because it is excluded from coverage for other reasons. These services include all services furnished in preparation for the use of a noncovered device, services furnished contemporaneously with and necessary to the use of a noncovered device, and services furnished as necessary after-care that are incident to recovery from the use of the device or from receiving related noncovered services.

(b) *When payment is made.* Medicare payment may be made for services, ordinarily covered by Medicare, to treat a condition or complication that arises